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Summary of Safety and Effectiveness

Submitted by:	CONMED Electrosurgery Division 14603 East Fremont Avenue Centennial, CO 80112 USA Telephone: 303-699-7600 Facsimile: 303-699-9854
Contact Person:	Pamela L. Vetter
Date Prepared:	January 24, 2005
Proprietary Name:	System 7500®-B ESU and ABCFlex™ Probe
Common Name:	Electrosurgical Unit and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and accessories (21 CFR 878.4400) 79 GEI
Predicate Device:	System 7500® Electrosurgical Unit, K981220, cleared 27-April-1998 ABC® Probe for Flexible Endoscopes, K990586, cleared 17-May-1999

K050161

Device Description: The System 7500®-B is an electrosurgical generator with Argon Beam Coagulation (ABC®) capability. The basic modes of operation are conventional electrosurgical cutting, coagulation plus argon beam coagulation. When cutting, the edge of the electrode is drawn across the tissue while electrosurgical energy is being applied. When coagulating, the accessory electrode or argon beam may be held in contact with the tissue for desiccation or separated from the tissue by distance for fulguration to achieve the desired result. The ABCFlex™ Probe has applications in endoscopic surgical procedures such as upper and lower gastroenterology and bronchoscopy to provide a means of coagulation using electrosurgical current and argon gas. The device consists of a connector for delivering argon gas to the operative site as well as an internal cable to carry high frequency (HF) electrosurgical current to a tungsten electrode tip at the end of the tubing. A ceramic tip insulates the thermal plastic tubing from the heat generated during coagulation. The electrode is positioned in the ceramic tip such that it cannot contact the patient's tissue during the coagulation procedure. Current and gas flow is controlled by the surgeon activating and deactivating a switching element part of the System 7500®-B ESU.

Intended Use of Device: The System 7500®-B is used for the destruction of human tissue in surgical procedures to provide a therapeutic benefit. The ABCFlex™ Probe is intended for use with the System 7500®-B for non-contact superficial ablation and hemostasis through a flexible endoscope to the operative site.

Technological Characteristics: The proposed devices are equivalent to the identified predicate devices with respect to technological characteristics and function. The devices have been designed to comply with the applicable sections of ANSI/AAMI American National Standard for Electrosurgical Devices HF-18, the International Electrotechnical Commission Standard for Electrosurgical Devices, IEC 60601-1, 60601-1-1, 60601-1-2, 60601-1-4, 60601-2-2, Sterilization of health care products – Requirements for validation and routine control of Ethylene Oxide Sterilization, ISO 11135 and Biocompatibility, ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Ms. Pamela Vetter
Manager of Regulatory Affairs
Conmed Electrosurgery
14603 E. Fremont Avenue
Centennial, Colorado 80112

Re: K050161
Trade/Device Name: System 7500® -B Electrosurgical Unit and ABCFlex™ Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 24, 2005
Received: January 25, 2005

Dear Ms. Vetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050161

Device Name: System 7500® -B Electrosurgical Unit and ABCFlex™ Probe

Indications for Use:

The System 7500® -B is used for the destruction of human tissue in surgical procedures to provide a therapeutic benefit. The ABCFlex™ Probe is intended for use with the System 7500® -B for non-contact superficial ablation and hemostasis through a flexible endoscope to the operative site.

Prescription Use X OR Over-The-Counter ____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050161